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(54) Intravascular endoprothesis.

(57) The intravascular stent intended for implantation in a stenotic area or zone of obstruction of a blood vessel consists of a flat sheet (1) which is perforated to form a kind of a reticulated or lattice type structure with undeformable links (2) and made of malleable material. Said sheet (1) is temporarily rolled up and locked in a spiral with a relatively small diameter (d) on a deflated angioplasty balloon (6) mounted on the end of a catheter (7) and is held in said rolled-up state by a tie (8) laced into overlapping links. Once the device is in place in the restricted area of the blood vessel to be treated and after tie (8) is removed, the rolled sheet (1) is expanded to a desired diameter (D) by inflating balloon (6) and is then held in this expanded state by integrated holding flaps (5) which, after the balloon is deflated, extend through the links and engage the edges thereof under the pressure of the vessel.

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INTRAVASCULAR ENDOPROTHESIS

BACKGROUND OF THE INVENTION

The present invention is directed to a cylindrically shaped, radially expandable intravascular endoprosthesis formed of biocompatible material. The device is intended to be transported and introduced into the area of stenosis or obstruction of a blood vessel by means of a catheter with a guidewire in a relatively tightly wound or rolled-up state. Means are provided to temporarily hold the endoprosthetic device or stent in a wound or rolled-up state around the catheter during transport and introduction into said area.

There are different kinds of intravascular endoprostheses, commonly called stents, which have the common characteristic of being presented into a patient's blood vessel or other body cavity or lumen in the shape of a cylindrical cuff, the wall of which forms a kind of lattice of deformable mesh in order to permit its diametrical expansion and contraction. In one of these types such as shown in U. S. Patent 4,740,207 (Kreamer), the stent is made of stainless steel sheet and appears originally in a rolled-up form of smaller diameter. After being introduced into the area of the vessel to be treated, it is expanded by means of an angioplasty balloon on the distal end of a catheter which is disposed on the interior of the rolled-up stent. The balloon is inflated with a fluid to the desired diameter which usually corresponds to the maximum expansion of which said balloon is capable.

In another type, such as described in U. S. Patent 3,868,956, and Japanese Application 57-89859 published June 4, 1982, the stent is made of thermo-expandable material such as nitinol which is dilated by heat after being implanted.

Finally, in a recently developed type, the stent is made of stainless steel wires of good elastic quality which are interwoven into a mesh, the diameter of which is selected to be slightly larger than the normal inner diameter of the vessel to be treated, so that it can exert a residual radial pressure on the arterial wall after being implanted. Before being introduced into the patient's blood vessel and while advancing the stent into the area of the blood vessel to be treated, the stent is reduced in diameter by stretching longitudinally and kept compressed on the catheter by a withdrawable sleeve. Once the device is implanted, the progressive withdrawal of said membrane permits the deployment of the stent in the vascular lumen.

Of these three known kinds of stents, the second, the one made of thermo-expandable material, presents the great inconvenience because it is difficult to manipulate and implant, and its expansion is hard to control and not reliable.

The above inconvenience does not exist in the stents made of stainless steel wire, but they still present a defect in that their expansion to a desired maximum diameter takes place at the cost of a proportional shortening of their length. This shortening, which follows the geometrical deformation of the lattice mesh being expanded in the transverse direction of the cylinder and reduced in the direction of its length, has the effect of making the accurate implantation of the device at its desired location very difficult.

The structure of an open weave, stainless steel wire results in loose wires at the ends of the cylinder which can be traumatizing to the arterial tissue and can result in a fibrous change therein and the formation of an intraluminal scar which can be the boginning of another stenosis.

The invention has the purpose of eliminating these inconveniences, particularly to provide a stent which can be easily and accurately placed in the desired arterial location with considerably less trauma than the prior art devices.

SUMMARY OF THE INVENTION

The intravascular endoprosthesis or stent according to this invention is characterized by the fact that it consists of a flat rectangular sheet intended to be rolled up into a spiral of small diameter around the catheter and held in the small diameter rolled-up state by a temporary holding means. It is then expanded to a greater diameter by unrolling, after the temporary holding means has been eliminated.

In this manner, the transition from the wound-up condition with a relatively small diameter to the unwound, expanded form of large diameter takes place without a reduction in the length of the endoprosthesis or stent because this dimensional change is obtained by unrolling rather than by dimensional deformation of its wall. This results in its implantation being simple and considerably more exact in the desired area.

Therefore, the use a woven metal wire structure is no longer necessary to obtain the expansion and/or reduction of diameter of the stent and this allows for the possible use of a plain sheet for special applications. However, when an open reticulated structure is required, it is still possible to provide the flat sheet forming the stent with apertures arranged to give it the appearance of a

lattice with regular non-deformable links.

In both cases, whether plain or perforated sheet is used, the surface of the stent wall is smooth and the ends of the sheet are free of metal fibers which result in it being implanted with little or no trauma to the blood vessel. Additionally, the flat inner surface of the stent makes for a smooth flow of the fluid.

These effects comply simply and reliably with the requirements set.

The advantages provided by this invention will be shown more clearly in the following detailed description, especially concerning the potential use of non-thrombogenic and degradable materials instead of stainless steel.

BRIEF DESCRIPTION OF THE DRAWINGS

The enclosed exemplary drawings show one embodiment of the invention and one structural variation thereof.

FIG. 1a is a schematic perspective view of a stent in a wound-up state embodying features of the invention;

FIG. 1b is a perspective view of the stent shown in FIG. 1a in an unwound, expanded state;

FIG. 2 is a transverse cross section of the embodiment shown in FIG. 1a;

FIG. 3 is a transverse cross section of the embodiment shown in FIG. 1a in an expanded condition;

FIG. 4 is a partial plan view of a structural detail of the wall of the stent shown in FIGS. 1-3; and

FIG. 5 is a partial view of structural details of a variation in the wall of the stent.

DETAILED DESCRIPTION OF THE INVENTION

The stent shown in FIGS. 1 to 4 consists of a flat rectangular sheet of biocompatible, malleable material, temporarily rolled up to form a cylinder 1 as shown in FIG. 1.

This rolled sheet 1 has an array of apertures which give it the appearance of a lattice 2 with non-deformable square links, the two parallel sides 3 of which are oriented in the longitudinal direction of the thus-formed cylinder. One angle of the reticulated structure is detailed in FIG. 4.

The covered edge 4 of the rolled sheet 1 is provided with holding flaps or fingers 5 which project outwardly from the longitudinal axis of the finished cylinder in order to engage links 2 of the latticework overlapping them.

In the embodiment shown, flaps 5 are spaced two by two within links 2 in order to facilitate their engagement in the latter.

In the left side of FIG. 1 and according to its section shown rolled up into a spiral having a relatively small diameter (d) over a deflated angioplasty balloon 6 which is mounted on the leading end of catheter 7; the two latter elements, the balloon and the catheter, being those commonly used for implantation of a stent.

The means to temporarily hold the stent in its rolled-up state is a holding wire 8 which is laced through the links of the last two layers of the spiral formed by the rolled sheet 1, close to the outer overlapping edge 9. The wire 8 is designed so that it can be removed by pulling from the outside.

In FIG. 1b, and according to its section shown in FIG. 3, the stent is shown in the expanded state with a larger diameter (D). It is expanded by inflating angioplasty balloon 6 after pulling out the holding wire. For the sake of clarity, balloon 6 and catheter 7 are not shown in FIG. 1b.

During inflation of the angioplasty balloon 6, the holding flaps 5 which are inclined in the direction opposite to that in which sheet 1 is unrolling, slide from link to link without engaging the latter.

When the angioplasty balloon 6 is deflated, the pressure of the blood vessel surrounding the stent has a tendency to re-roll the sheet 1 from which it is made. However, upon contraction of the sheet, holding flaps 5 which point in the direction of this re-rolling engage the first links of the lattice they encounter, hooking themselves into the edges of the latter, as can be seen in FIGS. 1b and 3. The stent is thus held firmly and cleanly without trauma in its expanded state in the vessel.

Of course, the rollable width of sheet 1 and the size of the lattice links are a function of the maximum diameter to which the angioplasty balloon 6 can be inflated and should be calculated so that after the maximum inflation of the balloon, edge 4 bearing flaps 5 is still overlapped by at least the last row of links of the opposite overlapping edge 9.

The design of the stent in a rolled sheet as described presents the advantage that it can easily be unrolled and rolled up on the angioplasty balloon 6 without modifying the latter.

The square form of links 2 of the lattice provides great radial stability of the cylinder, and that is of interest for the treatment of straight-line vessels. But the square form is not limitative.

Thus, for example, in order to facilitate the introduction of the endoprosthesis into an injured blood vessel, relatively high flexibility can be obtained with diamond-shaped links, such as links 10 of the variation shown in FIG. 5. In this alternative embodiment, the small axis (a) of the diamond-

shaped links point in the longitudinal direction of the cylinder.

The holding flaps intended to oppose the re-rolling tendencies of the stent under the pressure of the vessel after the angioplasty balloon 6 has been deflated are raised extensions 11 of the sharp angles of links 10 on the covered edge 4 of the sheet. The raised extensions 11 hook into the corresponding inner angles of the links which overlap them.

The holes which provide the rolled sheet 1 with a lattice-like or reticulated structure can have any desired geometrical shape, depending on the particular effect sought and the mode of application of the stent, without eliminating the lattice-like appearance. The principle of expansion by unrolling provides the advantage of preventing any shortening of the stent, whatever the shape of the apertures.

The drawing shows the favorable effect already indicated, as compared to the present state of the art, with an absence of free traumatizing wires at the ends of the stent cylinder, the latter presenting only geometrical elements, squares under 2 and diamonds under 10, the same effect being shared by all other shapes.

The system for holding the stent in its expanded state with a large diameter (D), which is effected by the self-locking holding flaps 5 and 11, eliminates the requirement for material with good elastic characteristics. This allows for the advantageous use of malleable and non-thrombogenic materials and eventually resorbable materials.

The holding system of the invention can also be used with a plain rolled sheet requiring only that perforations be provided for the flaps to engage in the overlapping edge of the sheet.

It is also possible to design a stent without overlapping the two longitudinal edges of the cylinder by providing gripping elements on both of the longitudinal edges which implant themselves in the wall of the vessel itself under the pressure of the latter.

Another advantage of this invention is that it permits the use of a stent formed of all kinds of materials such as metals and synthetic and ceramic materials, provided they are biocompatible.

The use of synthetic materials allows for a wider choice of a coating formed of compatible products or materials which prevent cell proliferation inside the stent.

In the case of a material having very good elastic characteristics it is possible to shape the cylindrical sheet 1 so that its expansion by unrolling is obtained by its own elasticity. The final shape of the expanded device has the appearance of an open cylinder.

Upon implantation, the elasticity of the material thus opposes itself to the pressure of the vessel until the two forces are in balance. In this embodiment, there is no need for means such as flaps 5 or 11, flaps 5 or 11.

Finally, other temporary means for holding the wound-up stent around the catheter can be used; for example, a cuff or points of degradable adhesive or a combination of adhesive points and wire 8 which detaches said points when it is pulled out.

Claims

1. A cylindrically shaped intravascular stent which may be positioned in an area of stenosis or obstruction in a blood vessel or other body lumen by mounting the stent on a catheter and advancing the catheter to the stenosis or obstruction over a guidewire and which has means to temporarily hold the stent in a first state of reduced diameter around the catheter during its advancement into said area and means to expand the stent when it is positioned in the area of stenosis or obstruction, characterized by the fact that the stent consists of a flat sheet (1) which is rolled up into a spiral having a reduced diameter (d) around a catheter (7) with overlapping inner and outer longitudinal sections and locked in that condition around the catheter by temporary holding means, means to release the temporary holding means and means to expand the stent to a larger diameter (D) by unrolling after releasing the temporary holding means so that there is an overlap of the longitudinal edges of said sheet, and then locking the stent in the expanded condition by means of radially extending fingers provided in the inner overlapping longitudinal section of the sheet which interfit through apertures provided in the outer overlapping longitudinal section of the sheet.

2. The stent according to claim 1 characterized by the fact that it is formed of elastic material and that its expansion by unrolling is caused by its own elasticity.

3. The stent according to claim 1 characterized by the fact that it is made of malleable material and that its expansion by unrolling is obtained by inflating an interior angioplasty balloon (6) mounted on and around the catheter.

4. The stent according to claim 1 characterized by the fact that the flat rolled sheet of which it consists has been equipped with holes so arranged as to give it a reticulated, lattice-like appearance with undeformable regular links (2,10).

5. The stent according to claim 4 characterized by the fact that it includes means to hold the stent in the expanded state by interlocking, consisting of a selected number of raised flaps (5,11) arranged projecting along the covered longitudinal edge (4) of the cylinder in the expanded state, pointing in a

radially outward direction to the latter and which extend through the first opening in the links they encounter in the overlapping sheet when the angioplasty balloon is deflated.

6. The stent according to claim 4 characterized by the fact that the links forming the rolled sheet are diamond shaped (10) with the small axis (a) thereof pointing in the longitudinal direction of the stent.

7. The stent according to claim 4 characterized by the fact that the links forming the rolled sheet are square-shaped (2) and the two parallel sides (3) thereof are oriented in the longitudinal direction of the stent.

8. The stent according to claim 1 characterized by the fact that the means to temporarily hold the stent in the rolled-up state around the catheter consists of a wire (8) laced through the links of at least the last two layers of the spiral formed sheet (1) rolled upon itself, said wire being designed to be removed from the outside.

Fig. 1a

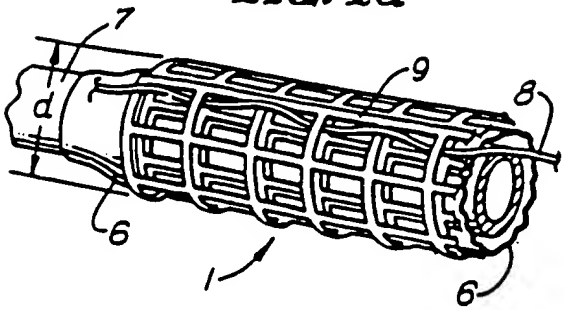


Fig. 1b

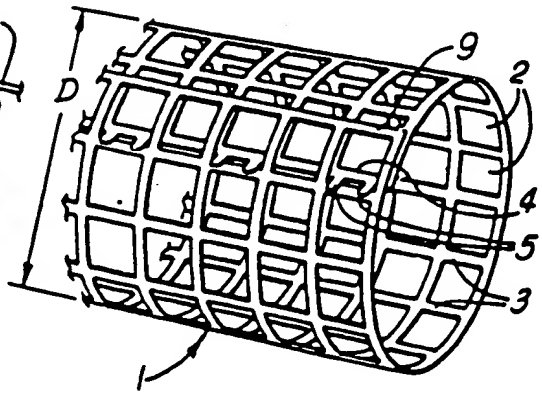


Fig. 3

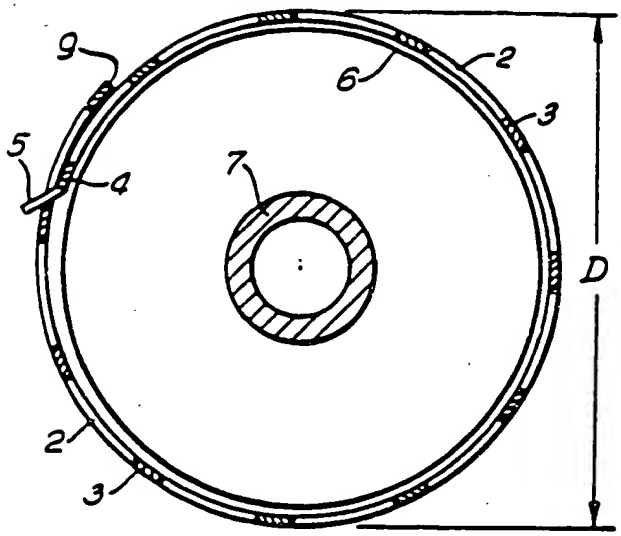


Fig. 2

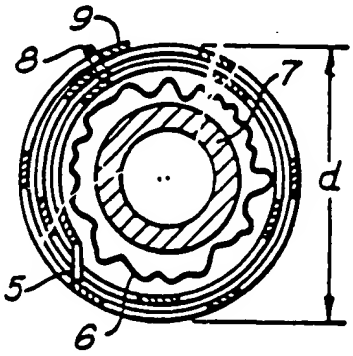


Fig. 4

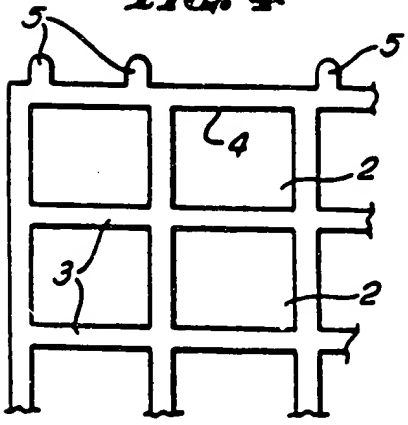
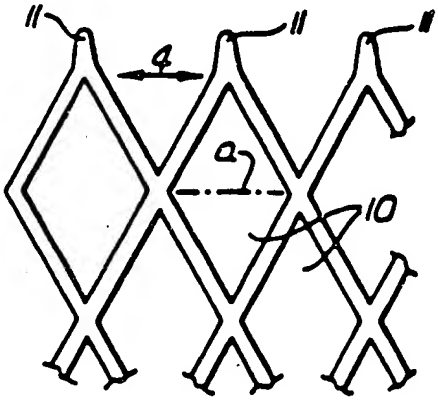


Fig. 5



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 90 10 1509

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	DE-A-3 640 745 (STRECHER) * Column 12, line 62 - column 13, line 20; column 11, lines 43-46; figures *	1,3,5	A 61 F 2/06
A	EP-A-0 246 998 (ZETA)		
A	EP-A-0 221 570 (PALMAZ)		
A	WO-A-8 300 997 (WALLSTEN)		
D,A	US-A-4 740 207 (KREAMER)		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F
A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	03-05-1990	STEENBAKKER J.

CATEGORY OF CITED DOCUMENTS

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